

REMARKS/ARGUMENTS

The rejections presented in the Office Action dated July 12, 2006 (hereinafter Office Action) have been considered. Claims 1-62 remain pending in the application. Claim 60 has been amended. Reconsideration of the pending claims and allowance of the application in view of the present response is respectfully requested.

The Applicants have amended the Specification to correct a typographical error. This change does not introduce new matter to the disclosure.

The drawings were objected to by the Examiner for failing to comply with 37 CFR 1.84(p)(5). Page 20, Line 9 of the Specification incorrectly listed a reference number as 105, a reference number which was not used in the drawings. This has been corrected in the above amendment to the Specification. As such, the Applicants request withdrawal of the objection to the drawings and acceptance of the originally filed drawings.

Claims 36-60 stand rejected under 35 U.S.C. §112, ¶2, as being indefinite for failing to particularly point out and distinctly claim the subject matter.

In regard to the §112, ¶2 rejection of claim 36, the Examiner states that the phrase “coupled to memory” is vague and that it is unclear if the memory is positively or functionally recited. The Applicants respectfully submit that skilled artisans know that memory is structure, and that a control system coupled to memory is a well understood structural arrangement.

In further regard to the §112, ¶2 rejection of claim 36, the Examiner states that it is unknown which element provides the atrial therapy referred to in claim 36. The Applicants respectfully submit that one of ordinary skill in the art would understand that a combination of the recited elements provides the atrial therapy referred to in claim 36. Moreover, the Applicant’s Specification provides further support for understanding claim 36 and resolving the Examiner’s stated concerns, including but not limited to Page 6, Lines 1-7; Page 6, Line 2 – Page 7, Line 2; Page 7, Lines 14-24 and Fig. 2.

In regard to the §112, ¶2 rejection of claims 37-39, the Examiner states that the phrase “the impedance threshold . . . lead impedance measurement” is vague and that it is

unclear which element is performing the function in each claim. Also, in regard to the §112, ¶2 rejection of claims 40-41, the Examiner states that the phrase “the impedance threshold . . . measure impedance” is vague and that it is unclear which element is performing the function in each claim. In further regard to the §112, ¶2 rejection of claims 46-48, the Examiner states that the phrase “the predetermined factor . . . the impedance threshold” is vague and that it is unclear which element is performing the function in each claim. The Applicants respectfully submit that one of ordinary skill in the art would understand that a combination of the recited elements measures impedance and stores the predetermined factor and impedance threshold. Moreover, the Applicant’s Specification provides further support for understanding claims 37-39, 40-41 and 46-48 and resolving the Examiner’s stated concerns, including but not limited to Page 6, Lines 8-15; Page 6, Line 21-Page 7, Line 2; Page 12, Line 4-Page 14, Line 17; Page 17, Lines 19-29 and Fig. 2.

In regard to the §112, ¶2 rejection of claim 49, the Examiner states that the phrase “a pace pulse” is vague and that it is unclear what element is providing a pace pulse. The Applicants respectfully submit that one of ordinary skill in the art would understand that the pace pulse is provided by a combination of the recited elements of independent claim 36 and dependent claim 49. Moreover, the Specification provides further support for understanding claim 49 and the pace pulse, including but not limited to Page 20, Lines 8-13.

In regard to the §112, ¶2 rejection of claim 50, the Examiner states that the phrase “a stimulus delivered” is vague and that it is unclear what element is providing a stimulus. The Applicants respectfully submit that one of ordinary skill in the art would understand that the stimulus is provided by a combination of the recited elements of independent claim 36 and dependent claim 50. Moreover, the Specification provides further support for understanding claim 50 and the stimulus, including but not limited to Page 6, Lines 1-7; Page 6, Line 2 – Page 7, Line 2; Page 7, Lines 14-24; Page 13, Line 29-Page 14, Line 5 and Fig. 2.

In regard to the §112, ¶2 rejection of claims 51 and 53, the Examiner states that the phrase “after detection of an atrial arrhythmic event” is vague and that it is unclear what element is providing detection of an atrial arrhythmic event. An atrial arrhythmic event is not something provided by the elements of the claims, but rather is something to which the elements of the claims are responding. Also, the Applicants respectfully submit that one of ordinary skill in the art would understand that detection of an atrial arrhythmic event is provided by a combination of the recited elements of dependent claims 51 and 53, respectfully, and independent claim 36. Moreover, the Specification provides further support for understanding claim 51 and the detection of an atrial arrhythmic event, including but not limited to Page 6, Line 8-Page 9, Line 4; Page 19, Lines 25-30 and Fig. 2.

In regard to the §112, ¶2 rejection of claims 52 and 54, the Examiner states that the phrase “after detection of an atrial arrhythmic episode” is vague and that it is unclear what element is providing an atrial arrhythmic episode. The recitation of an atrial arrhythmic episode in claims 52 and 54 is not included as an element or as a function within the claim. Rather, one of ordinary skill in the art would understand that an atrial arrhythmic event is something to which the elements of the respective claims are responding.

In regard to the §112, ¶2 rejection of claim 60, claim 60 has been amended to depend from claim 55, which provides antecedent basis for elements of claim 60. This amendment corrects a typographical error and does not narrow the scope of claim 60.

As such, the Applicants submit that claims 36-60 are in compliance with §112, ¶2 and request withdrawal of the §112, ¶2 rejections to claims 36-60.

Claims 1-3, 10-19, 20, 24-27, 36-39, 44-55 and 59-62 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 7,031,773 to *Levine et al.* (hereinafter “*Levine*”).

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either

expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Therefore, all claim elements, and their limitations, must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102. The Applicants respectfully submit that *Levine* does not teach each and every element of independent claims 1, 20, 36, 61 and 62, and therefore fails to anticipate these claims.

Levine discloses an autocapture technique where an impedance measurement circuit takes an impedance measurement of a lead "whenever there is a failure to detect an evoked response (presumed loss of capture)". (Col. 10, Line 64-Col. 11, Line 4). If an impedance measurement "falls outside of a predetermined or programmable impedance range," then the electrode configuration will be changed and capture will again be attempted. (Col. 11, Lines 10-31). The electrode configuration changes of *Levine*'s autocapture technique include using a single electrode instead of two and increasing the electrode output and reattempting capture (Col. 11, Lines 19-31).

Applicant's independent claims 1, 20, 36, 61 and 62 each include, among other limitations, some variation of disabling atrial antitachycardia pacing (ATP) therapy in response to a measured impedance deviating from a threshold.

Levine fails to teach or contemplate disabling ATP therapy for any reason. *Levine* clearly fails to teach disabling ATP therapy in response to a measured impedance deviating from a threshold.

Furthermore, while Applicant's independent claims 1, 20, 36, 61 and 62 include disabling ATP therapy, *Levine* discloses continuing capture detection with one less electrode and/or increasing the intensity of the electrical stimulation.

Applicant's independent claims 1, 20, 36, 61 and 62 are clearly distinguishable over the *Levine* reference when these claims are viewed in light of Applicant's Specification. Applicant's Specification teaches that atrial lead dislodgement can cause unintended and dangerous delivery of atrial antitachycardia therapy to the ventricle. (Page 10, Lines 8-27). In such a case, disabling ATP pacing therapy is effected, which is contrary to *Levine*'s

teaching of continuing with a capture detection procedure. (Page 10, Lines 8-Page 11, Line 8).

In addition, Applicant's independent claims 1, 36 and 61 each recite, among other limitations, some variation of an impedance threshold developed for a particular patient.

Levine discloses "a predetermined or programmable impedance range" that when exceeded indicates a lead failure. (Col. 11, Lines 11-15). *Levine* does not disclose an impedance threshold developed for a particular patient. *Levine* does disclose customizing specified parameters for a particular patient. (Col. 8, Line 65-Col. 9, Line 7). However, these customizable parameters specified by *Levine* only include parameters for detecting arrhythmia and delivery of a therapy (i.e. pulse amplitude, duration, rate, etc.) and do not include an impedance threshold developed for a particular patient. *Id.*

Applicant's independent claims 20 and 62 recite, among other limitations, some variation of measuring an impedance, a capture threshold, and a sense amplitude, respectively associated with an atrial lead and comparing the impedance, capture threshold, and sense amplitude measurements with impedance, capture threshold, and sense amplitude limits, respectively.

Levine discloses an autocapture technique which enables an impedance measuring circuit "whenever there is a failure to detect an evoked response (presumed loss of capture)." (Col. 11, Lines 1-3). *Levine*'s impedance measuring circuit then takes an impedance measurement and compares the measurement to a predetermined range. (Col. 11, Lines 4-15). *Levine* does not teach measuring a sense amplitude, nor does *Levine* teach comparing a capture threshold with a capture threshold limit or comparing a sense amplitude measurement with a sense amplitude limit.

In light of the above arguments, the Applicants respectfully submit that the *Levine* reference does not teach each and every element and limitation of independent claims 1, 20, 36, 61 and 62. As such, these claims are not anticipated by *Levine* and the anticipation rejection of these claims must be withdrawn.

Dependent claims 2-3, 10-19, 24-27, 37-39, 44-55 and 59-60, which are dependent from independent claims 1, 20, 36, 61 and 62, respectively, were also rejected under 35

U.S.C. §102(e) as being unpatentable over *Levine*. While the Applicants do not acquiesce with the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claims 1, 20, 36, 61 and 62. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited reference. Therefore, dependent claims 2-3, 10-19, 24-27, 37-39, 44-55 and 59-60 are also not anticipated by *Levine*.

As such, the Applicants respectfully request withdrawal of the §102(e) rejection of claims 1-3, 10-19, 20, 24-27, 36-39, 44-55, and 59-62 and notification that these claims are in condition for allowance.

Claims 4-8, 21-23, 28-29, 40-43 and 56-58 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Levine*.

Three criteria must be met to establish a prima facie case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all the claim limitations. MPEP § 2142.

Each of claims 4-8, 21-23, 28-29, 40-43 and 56-58 depend from one of independent claims 1, 20 and 36, respectively. Independent claims 1, 20 and 36 are not obvious for at least the reason that *Levine* fails to teach or suggest each and every limitation recited in each claim. Furthermore, while the Applicants do not acquiesce with the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claims 1, 20 and 36. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited reference. Moreover, if an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir.

1988). Therefore, dependent claims 4-8, 21-23, 28-29, 40-43 and 56-58 are not made obvious by *Levine*.

As such, the Applicants respectfully request withdrawal of the §103(a) rejection of claims 4-8, 21-23, 28-29, 40-43 and 56-58 and notification that these claims are in condition for allowance.

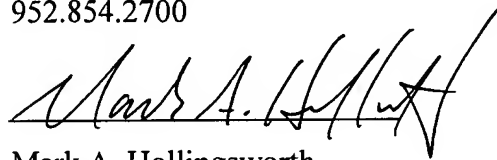
Authorization is given to charge Deposit Account No. 50-3581 (GUID.014US01) any necessary fees for this filing. If the Examiner believes it necessary or helpful, the undersigned attorney of record invites the Examiner to contact him to discuss any issues related to this case.

Respectfully submitted,

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